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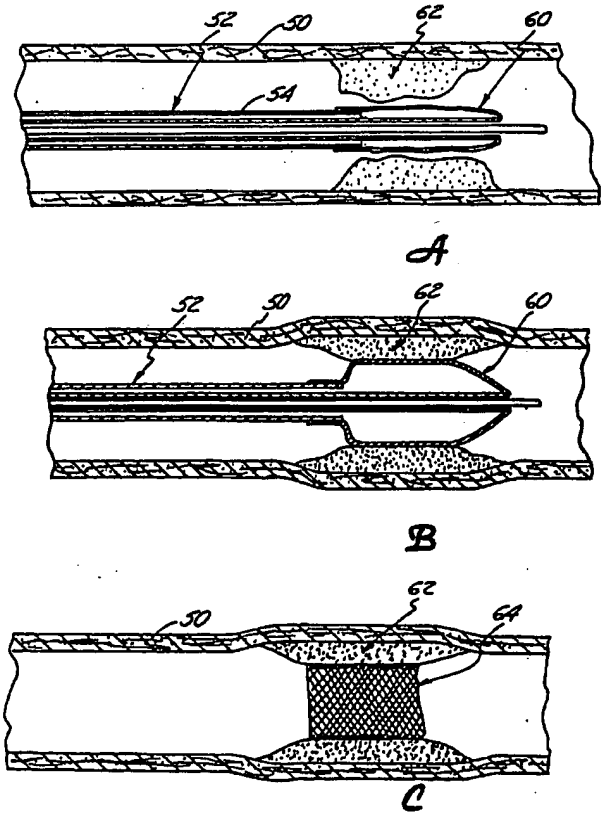
(57) Abstract

An improved medical device (64, 100, 120, 122, 160) is inserted into a body cavity of a patient for treatment. The medical device (64, 100, 120, 122, 160) is formed of a beta–titanium alloy composition which is designed to provide desired operating characteristics in the operating environment based upon the application of the medical device (64, 100, 120, 122, 160).



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MEDICAL APPARATUS FORMED OF BETA-TITANIUM ALLOYS

BACKGROUND OF THE INVENTION

The present invention relates to improved implantable devices or devices inserted into a body tract or a body cavity of a patient. In particular, the present invention relates to an improved material construction for implantable or insertable devices for desired corrosion resistance, material properties and biocompatibility.

Various types of medical procedures are known which utilize temporary or permanent structures which are inserted into a body cavity for treatment. In particular, various types of catheters are known for treating cardiac or other disorders, by temporarily inserting catheters into the vascular system, the urinary tract, or other such tracts, such catheters include angioplasty catheters, which are used to dilate restricted coronary vessels or to treat other ailments. It may well be important that such devices are corrosion resistant, depending upon the environment in which they are used. It is also typically important that such devices be biocompatible.

Further in catheter applications, it is desirable that the shaft supporting the catheter have sufficient rigidity for pushability and torqueability, as well as sufficient flexibility to prevent kinks. Prior catheter shafts have been formed of polymer materials, metals, metal alloys such as Nitinol, or have been formed as a hypotube. A hypotube is relatively stiff and provides desired pushability and torqueability, but generally is less flexible and has

increased kinkability. Such hypotubes have typically been formed of a stainless steel material.

Of course, many other catheters are conventionally used as well. Such catheters include infusion catheters, perfusion catheters, drainage catheters, neural catheters, drug delivery catheters, guide catheters, stent delivery catheters, etc... Further, many other types of elongate medial devices are used as well. Some such devices include guidewires, atherectomy devices, etc.

Other medical devices include implantable devices which are permanently implanted, such as stents and filters. It is important that such medical devices be compatible and also have permanency for extended use in the body cavity environment. Therefore, it is desirable to engineer medical devices for permanent implantation so the devices are formed to withstand adverse implantation environments for long-term wear and durability for long-term treatment success. Additionally, it is important that the material in medical devices be biocompatible with the treatment environment and have sufficient strength for operation and long-term deployment. Stents and filters can be made of stainless steel material, or alternatively, can be made of shape-memory alloys, such as Ni-Ti, or copper-based shape-memory alloys such as Cu-Al-Ni or Cu-Zn-Al.

SUMMARY OF THE INVENTION

The present invention relates to medical devices adapted for insertion into a patient's body cavity or vasculature, formed of a beta-titanium alloy, having an alloyed composition providing desired operating characteristics for the particular operating environment. In particular, in one embodiment of the

invention a stent is formed of an alloyed beta-titanium composition providing pseudoelastic attributes in a usable operating range for inserting and deploying the stent. In another embodiment, an alloyed composition of beta-titanium can be designed to provide superelastic characteristics for desired operating characteristic and elasticity for kink resistance for elongated devices inserted into a body cavity for use.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. 1A-1C illustrate an intravascular procedure for treatment of an occluded vessel and deployment of a stent.

FIG. 2 is an embodiment of a stent in accordance with one aspect of the present invention illustrated in a collapsed condition for low profile insertion.

FIG. 3 illustrates the stent of FIG. 2 in an expanded deployed position.

FIG. 4 illustrates an embodiment of an insertion device for insertion and deployment of an embodiment of a stent of the present invention in a vessel.

FIG. 5 illustrates an alternative embodiment of an insertion device for insertion and deployment of an embodiment of a stent of the present invention in a vessel.

FIG. 6 illustrates an embodiment of a guidewire in accordance with one aspect of the present invention.

FIGS. 7A-7B illustrate an embodiment of an over-the-wire catheter according to one aspect of the present invention.

FIGS. 8A-8B illustrate an embodiment of a single-operator-exchange catheter according to one aspect of the present invention.

FIG. 9 illustrates an embodiment of a vena cava filter for trapping blood clots and debris according to one aspect of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention relates to improved implantable or insertable devices for medical treatment. One embodiment of the present invention relates to an intravascular stent to maintain or hold a dilated vessel in an opened non-occluded condition. Self-expanding or balloon deployable stents are known. Stents may be used and deployed to support various types of body passageways including, for example, esophagus, the intestines, vascular lumens, the ureter, the urethra, as well as other body passageways.

FIGS. 1A-1C illustrate a treatment process for an occluded vessel 50. Preferably, the occluded vessel is initially opened or dilated by known angioplasty techniques as illustrated in FIGS. 1A-1B. In particular, a dilatation catheter 52 including a shaft 54 and a dilatation balloon 60 is fed through an occluded vessel 50 to locate balloon 60 relative to a lesion 62 (e.g., an occlusion, or a complete restriction). Balloon 60 is inflated to compress the balloon 60 into the vascular wall 50 (or compress the plaque or occlusion) and expand the vessel wall 50 to open the constriction caused by the stenosis 62 as illustrated by FIG. 1B. Thereafter, inflation pressure is released, and the balloon 60 is deflated for withdrawal.

After the restriction or occlusion 62 is opened, a stent 64 may be deployed to retain the

stenosis 62 in a nonoccluded position. The stent 64 is inserted into the patient and deployed at a treatment site or lesion as illustrated in FIG. 1C to maintain the vessel 50 in an opened nonoccluded position. The stent 64 is inserted in a collapsed condition and is aligned relative to lesion 62. Once, the stent 64 is aligned relative to the lesion 62, the stent 64 is deployed to the deployment diameter illustrated in FIG. 1C. This can be done in any of a variety of ways including methods described herein.

FIGS. 2 & 3 illustrate one embodiment of stent 64 in accordance with one aspect of the present invention. Stent 64 is formed of a tubular member 66 constructed of a mesh-like material which is adapted to expand between a low profile insertion dimension as illustrated in FIG. 2, and an expanded dimension for deployment as illustrated in FIG. 3. In the expanded diameter the stent 64 is sized relative to the body lumen to interact with the vessel walls to maintain the vessel walls in an open, nonoccluded position.

For operation, it is important that the stent be easily expandable and have sufficient rigidity in an expanded deployed state to maintain an occluded vessel (or other tract or body cavity) in an opened, nonoccluded condition. After deployment, the elasticity of the stent should allow flexure of the stent to avoid discomfort to the patient or harm to vessel. The stents are used in body cavities; and, accordingly, it is necessary that the stent be biocompatible with the patient and the body cavity and not react or breakdown in the environment of use.

Prior art stents have been made of a stainless steel material which plastically deforms upon sufficient pressure to conform to the vessel wall to hold the

vessel wall open for desired blood flow. In such stent devices, permanent deformation is achieved when the material is subjected to a force which creates a strain greater than the elastic limit of the material. Exceeding the elastic limit of such materials is believed to compromise the performance of such devices.

Other stents are formed of shape-memory alloys which are positioned within the body and deployed via thermal activation to expand the stent and cause it to conform to the opened stenosis. One way and two way shape-memory alloys are known which exhibit shape memory characteristics in a martensite metallurgic phase. Known shape-memory alloys for implantable or insertable medical devices include binary nickel titanium Ni-Ti (nitinol), Ni-Ti-x ("x" being V. Co. Cu. Fe.); Cu-Al-Ni; or Cu-Zn-Al.

For example, U.S. 5,562,641, Flomenblit discloses a two way shape memory alloy stent formed of binary nickel titanium Ni-Ti (nitinol), Ni-Ti-x ("x" being V. Co. Cu. Fe.); Cu-Al-Ni; or Cu-Zn-Al. Prior to insertion, the stent is cooled below a transition temperature in the range of -10 to 20 degrees C to transition the stent to a collapsed diameter for insertion. The stent is inserted in a cooled collapsed condition so it can be located at a treatment site. The stent is deployed to an expanded configuration to conform to the treatment organ diameter by heating the stent above a transition temperature of 40-80 degrees C. To remove the stent, the stent is again cooled below transition temperature -10 to 20 degrees C to collapse the stent for removal.

U.S. Patent No. 5,545,210 discloses an alternate stent design formed of a shape memory alloy such as binary Ni-Ti alloy, Ni-Ti-x or Cu-Al-Ni. The

stent is collapsed for insertion by mechanically deforming the stent to a collapsed position in the martensite crystalline phase. Preferably, the stent is deformed in the temperature range below 37 degrees C. The stent is introduced for placement at a treatment site and is heated above body temperature to a transition temperature in a temperature range of 37 -62 degrees C to expand the stent in the austenite condition to the memorialized expanded diameter. Thereafter, the stent cools to body temperature to function in a martensitic condition. In addition to application of heat, the stent may be expanded via application of mechanical pressure via a balloon.

Stents are designed to continuously operate in a stenotic vessel to maintain the vessel in a nonoccluded, open condition subsequent to a dilatation operation. Thus, in some applications it is important that, once the stent is deployed, tissue grows around the stent so that the stent forms with the vessel wall at the treatment site. It is important, for the health of the patient, that the stent be biocompatible with the vessel of the patient. Materials such as titanium provide excellent corrosion resistance to protect the health of the patient. However, other elements may introduce toxins to the patient.

In the embodiments of the stent of the present invention illustrated in FIGS. 2-3, the stent is formed of a beta-titanium alloy, such as titanium containing alloyed elements such as molypedenum, zirconium, niobium, tantalum, or iron to provide an alloy with superelastic characteristics in a desired operating range. Superelasticity relates to significant strain under constant load with complete elastic recovery for placement and deployment of the stent.

Beta phase titanium is a body-centered cubic crystalline structure. At room temperature, titanium exists in alpha phase in a closed-packed hexagonal structure. Titanium crystalline structure changes at about 884 degrees C to beta phase. Alloying elements such as copper, chromium, iron, molybdenum, and vanadium beta stabilizers lower the transformation temperature of an alpha phase titanium to a beta phase titanium to remain stable at lower temperatures, even at room temperature. Such beta-titanium alloys generally provide high strength, a relatively low modulus of elasticity, and excellent corrosive resistance for operation in a vascular lumen or other body cavity, such as the esophagus.

The stent according to the present invention preferably is formed of a superelastic beta-titanium alloy which has a low modulus of elasticity and elastic recovery in the operating range so that the stent 64 may be easily stretched (as illustrated by arrows F in FIG. 3) for low profile insertion as illustrated in FIG. 2 and elastically recovered to an expanded diameter for deployment as illustrated in FIG. 3. Preferably, the stent is mechanically crimped to a distal end of a stent deployment apparatus for low-profile insertion. Since the stent is formed of a material with a low modulus of elasticity and is superelastic, stent may be easily stretched to the low-profile dimension and easily mounted in the low-profile dimension without significant tension for low profile insertion and deployment.

During insertion, stent 64 is retained in the low-profile dimension for placement at a deployment site. Stent 64 is deployed at a treatment site by releasing the stress or tension maintaining the stent in a low-profile dimension so that the stent 64 resumes an

expanded dimension profile as illustrated in FIG. 3. Since the stent is formed of a superelastic beta-titanium alloy, once the tension is released, the stent elastically returns to its original expanded diameter shape. In the expanded diameter shape shown in FIG. 3, the stent 64 is sized to conform to a vessel wall or cavity wall for operation as illustrated in FIG. 1C. The implanted stent-like member allows for a small amount of radial recovery when deflected at low loads as the supported duct or cavity contracts. The low force needed to cause elastically-recoverable deflection of stent-like members in response to tissue duct contraction can advantageously minimize the irritation to the duct walls wherein small contractions occur.

The lower modulus of elasticity allows the stent to easily deform to reduce discomfort and increase puncture resistance. Beta-titanium alloys have excellent formability, corrosive resistance, and limits certain toxic elements. An example of a beta-titanium alloy comprises the following components, by weight: molybdenum - 8 to 12%; aluminum - 2.5 to 4%; chromium - 1.4 to 2%; and niobium - 3.0 to 9.5%, balance titanium. An alloy with 11% molybdenum; 3% aluminum; 2% vanadium, and 4% niobium, balance titanium is preferred. A number of beta-titanium alloys are available from Memory Corporation of Brookfield, Connecticut.

FIGS. 4-5 illustrate alternate embodiments of a stent deployment apparatus for low-profile insertion of stent 64. As shown in FIG. 4, stent 64 is inserted via a deployment apparatus 70 including a support sheath 72 and an outer deployment sheath 74. Sheath 72 is a tubular member defining a lumen (not shown) extending therethrough for advancement over a guidewire 78. Stent 64 is crimped to and supported about an outer diameter

of sheath 72 in a low-profile dimension. Sheath 74 is formed of a tubular member having a central lumen 80 sized to extend about sheath 72 and low-profile stent 64 to retain the stent in the low-profile dimension. To deploy stent 64, sleeve or sheath 74 is withdrawn proximally from stent 64 as illustrated by arrow 82 to release the compression force to stent 64 so that stent 64 elastically recovers to its original expanded diameter. Once the radial pressure is released, the stent elastically recovers, or "springs," to its original pre-stressed expanded profile for deployment as illustrated in FIG. 1C.

In particular, a distal end of sheath 74 extends about stent 64 supported at the distal end of sheath 72 to maintain stent 64 in a collapsed low profile for insertion. Thereafter, sheath 74 is withdrawn for deployment of stent 64. The stent 64 is inserted and advanced to a deployment site via apparatus 70 as illustrated in FIG. 4 while sleeve or sheath 74 maintains stent in a collapsed low profile for insertion.

An alternate deployment apparatus 84 is illustrated in FIG. 5. As shown, device 84 is formed of a tubular member having an inner lumen 86, a proximal end (not shown) and a distal end 88. Tubular member includes a first diameter portion 90 at distal end 88, and a second diameter portion 92 supporting ring tab 94 extending distally from an end of the second diameter portion 92 and opened at a distal end.

The stent 64 is supported at a distal end 88 of first diameter portion 90 in the collapsed profile. In particular, normally expanded stent is stretched and crimped down about first diameter portion 90. Ring tab 94 extends about a portion of collapsed stent 64. An

inner diameter of ring tab 94 is sized to retain stent in a crimped low profile. As shown in FIG. 5, stent 64 is advanced via apparatus 84 to a deployment site for deployment. Once stent 64 is positioned at a deployment site, apparatus 84 is withdrawn proximally as illustrated by arrow 96. As apparatus 84 is withdrawn proximally, stent 64 slides off portion 90 through an end opening 90 of tab 94 so that tab 94 no longer maintains stent 64 in the collapsed profile and stent elastically recovers and expands to conform to the profile of the lumen of the vessel at the deployment site. Although example deployment devices are shown, it should be understood that alternate deployment devices may be used including balloon-type deployment devices and the invention is not limited to any particular deployment device.

Although FIGS. 2-3 illustrate a particular embodiment of a stent, the invention is not limited to the particular design shown, and alternate stent embodiments may be employed such as for example, a coil stent, a tubular stent or a tubular stent having perforations for expansion. Additionally it should be understood that the stent is not limited to any particular stent and that stents of the present invention may be used in many body cavities or tracts, such as the coronary vessels, esophagus, or urinary or urethral tracks where the operating environment is acidic or corrosive and enhanced corrosive resistance is desired.

Guidewires are known and are typically used for medical treatment to aid with insertion and placement of medical devices. Guidewires may be formed of a solid core wire or a solid core wire surrounded by a coiled wire, or a tubular member. Hollow guidewires

can also be used for drug delivery, to take pressure measurements, and to support distal protection or other devices. In particular, guidewires may be used in an angioplasty procedure to guide a dilatation catheter to a treatment site or in gastrointestinal procedures to accomplish a number of tasks. When used for coronary or intraluminal procedures, it is desirable that the guidewire have a small diameter, a smooth finish, and have desirable pushability, torqueability and kink resistance. When used in gastrointestinal procedures, guidewires preferably have high corrosion resistance.

Pushability refers to the ability of the wire to transfer axial force applied to the proximal end for placement of the guidewire. Torqueability relates to the ability of the guidewire to transfer torque or rotation along the length of the guidewire for manipulating the guidewire for placement at a treatment site and is related to the torsional rigidity of the guidewire. Kink resistance is the measure of the ability of a guidewire to be forced into a relatively tight bend radius without permanently deforming the wire. In order to steer a guidewire through a tortuous vessel, sufficient kink resistance is desired so that the device does not kink or permanently deform, thus degrading trackability and operation of the guidewire through a patient's vascular system.

Conventional guidewire cores have been made of carbon or stainless steel. Guides wires have also been made of super-elastic alloys, such as Ni-Ti alloys. FIG. 6 illustrates an embodiment of a guidewire 100 of the present invention. As shown, the guidewire 100 includes an elongated constant diameter core portion 102, a transitional portion 106, and a flexible distal tip 108, and is relatively stiff and rigid for adequate

pushability. Relatively flexible distal tip is preferably formed of an elastic more flexible cylindrical member so that the tip of the guidewire bends under small loads to navigate through tortuous vessels to a treatment site.

In the embodiment shown, the guidewire (core portion 102, transition portion 106, and distal tip 108) is preferably formed of a beta-titanium alloy which has superelastic properties. The superelastic characteristic properties provide desirable kink resistance. The superelastic or pseudoelastic properties allow the guidewire to be pushed into a tight bend and to absorb force without permanent deformation. In particular, superelasticity allows relatively large strain at a constant load for tracking a guidewire through a tortuous vascular system. Thus, the guidewire may be readily bent and straightened without deformation to reduce resistance to advancement of the guidewire.

Core portion 102, as shown, is formed of a solid cylindrical member having a sufficient diameter to provide rigidity for advancing the guidewire. Flexible tip 108 is sized smaller than core portion 102 to provide a flexible tip which can be forced into tight bends for navigation. As previously explained, flexible tip 108 is straightened after force is released for continued operation. Transition portion 106 is an elongated tapered member to provide a gradual connection between the larger, more rigid core portion 102 and the smaller, more flexible tip 108.

Distal tip 108 is preferably formed of a beta-titanium alloy having a relatively low modulus of elasticity to deform at low loads so that the distal tip 108 may be easily bent to curve through blood vessels in

order to wind to a treatment site. Thus, the distal tip can be easily curved according to the vascular branching and returns to its original unstrained position once the flexure force is removed. Preferably, core portion 102 may be formed of a beta-titanium having a higher modulus of elasticity for pushability and trackability of the guidewire 100.

Preferably, the distal tip is shaped or preformed for insertion in any number of known shapes such as an "R" shape, "J" shape or other shapes. Also, in a preferred embodiment, the beta-titanium alloy guidewire may be coated with a polymer coating such as polytetrafluoroethylene (PTFE). The guidewire described has desired operating characteristics for inserting the guidewire through a patient's vasculature for tracking the guidewire to a treatment site and is formed for biocompatibility with the operating environment. Although in the embodiment described, the core member 102 and distal tip 108 are formed of a beta-titanium alloy, the invention is not so limited and the guidewire may be formed of a composite structure.

Various types of catheters are known for treating medical ailments and are inserted in a patient for treatment. For example, such devices include vascular catheters and other catheters (mentioned in the background portion of the specification) formed of elongated tubular members which are advanced through a patient. The tubular members may be formed of a plastic material or may be a stainless steel hypotube. Vascular catheters are advanced a sufficient distance to a treatment site and must have pushability, torqueability, and kink resistance for suitable operation.

FIGS. 7A-7B and 8A-8B illustrate vascular catheters 120 and 122 adapted for use as dilatation catheters. FIGS 7A-7B illustrate an over-the-wire catheter 120 having a catheter shaft 123, a proximal manifold 124 and a distal dilatation balloon 126. A guidewire 100 extends through the catheter 120 to track the catheter 120 to a treatment site in a known manner. Manifold 124 includes an inflation port 128, a guidewire port 130 and a flush port 132.

As illustrated in FIG. 7B, the catheter shaft 123 includes an inner tube 134 and an outer tube 136 concentrically aligned about the inner tube 134. A lumen 140 extending through inner tube 134 forms the guidewire lumen. As shown, balloon 126 is coupled to distal ends of inner tube 134 and outer tube 136 and a lumen 142 formed between inner and outer tubes 134, 136 defines the inflation lumen. In the over-the-wire catheter of the present invention, the inner tube 134 or outer tube 136 (or both) is formed of a beta-titanium material. The beta-titanium material has a relatively low modulus of elasticity and pseudoelastic characteristics for tracking through tortuous vascular without permanent bending or deformation. Alternatively, tubes 134, 136 may be formed of a composite (polymer/alloy) structure to provide desired rigidity and flexibility along the length of the catheter to track the catheter to the treatment site as disclosed in U.S. Patent No. 5,549,552, Peters et al. which is hereby incorporated by reference, the alloy portion of which is formed of beta-titanium in accordance with the present invention.

FIGS. 8A-8B illustrate a single-operator-exchange catheter 122 including a distal guidewire lumen 144. Catheter 122 includes shaft 146, manifold 148 and

balloon 150. Manifold 148 includes an inflation lumen for inflating balloon 150 at the distal end. As illustrated in FIG. 8B, shaft 146 is formed of elongated tubular extent 152 having an inflation lumen 154 extending therethrough. A distal portion of the shaft 146 is formed of an inner tube 156 forming the guidewire lumen 144 extending along a distal extent of the catheter and an outer tube 158 enclosing inner tube 156 and coupled to proximal tubular extent 152.

The extent between the inner and outer tubes 156, 158 defines the inflation lumen 154 of the distal extent of catheter 122. Balloon 150 is coupled to distal ends of inner and outer tubes 156 and 158 and inflation pressure is supplied through the inflation lumen 154 to inflate the balloon for use. Tubular extent 152 or inner or outer tubes 156, 158 (or all) are formed of a beta-titanium alloy. The beta-titanium alloy has pseudoelastic characteristics and for providing desired kink resistance, as well as allowing the catheter 122 to pseudoelastically deform under constant load for tracking catheter 122 to a treatment site.

Other medical devices such as a vena cava filter 160 for trapping blood clots in a vessel, an embodiment of which is illustrated in FIG. 8 may be formed of a beta-titanium alloy. Vena cava filter 160 can be collapsible for insertion and expandable for deployment.

Although the present invention has been described with reference to preferred embodiments, workers skilled in the art will recognize that changes may be made in form and detail without departing from the spirit and scope of the invention.

WHAT IS CLAIMED IS:

1. An implantable stent comprising:

a tubular member formed of a beta-titanium alloy composition having superelastic characteristics in a characteristic range to allow the tubular member to be elastically deformed to the insertion diameter and expanded to a deployment diameter via operation of the superelastic characteristics.

2. The stent of claim 1 wherein the beta-titanium alloy composition includes: molybdenum, aluminum, chromium, and niobium.

3. The stent of claim 1 wherein the beta-titanium alloy composition includes: molybdenum - 8 to 12%; aluminum - 2.5 to 4%; chromium - 0 to 2%; vanadium - 1.4 to 2% and niobium - 3.0 to 9.5%, balance titanium, by weight.

4. The stent of claim 1 wherein the beta-titanium alloy has relatively low modulus of elasticity.

5. The stent of claim of claim 1 wherein the tubular member is formed of a mesh material.

6. A guidewire adapted for transluminal insertion into a body of a patient, comprising:

an elongated core member and a flexible distal tip, at least one of said core member and distal tip being formed of a beta-titanium alloy composition.

7. The guidewire of claim 6 wherein the core member is formed of the beta-titanium alloy composition and has super-elastic characteristics for kink resistance.

8. The guidewire of claim 6 wherein the distal tip is formed of the beta-titanium alloy and has super-elastic characteristics for kink resistance.

9. The guidewire of claim 6 wherein the beta-titanium alloy composition includes: molybdenum - 8 to 12%; aluminum - 2.5 to 4%; chromium - 0 to 2%; vanadium - 1.4 to 2% and niobium - 3.0 to 9.5%, balance titanium by weight.

10. A catheter adapted for insertion into a patient comprising:

an elongated tubular member having a proximal end and a distal end, at least a portion of said tubular member being formed of a beta-titanium alloy composition.

11. The catheter of claim 10 wherein the elongated tubular member includes a balloon supported at a distal end and coupled to an inflation lumen formed via the tubular member, the inflation lumen being adapted to supply inflation pressure for inflating the balloon.

12. The catheter of claim 10 wherein the beta-titanium alloy has super-elastic characteristics for kink resistance.

13. The catheter of claim 10 wherein the beta-titanium alloy composition includes: molybdenum - 8 to 12%; aluminum - 2.5 to 4%; chromium - 0 to 2%; vanadium - 1.4 to 2% and niobium - 3.0 to 9.5%, balance titanium by weight.

14. A medical device adapted for insertion into a cavity of a patient, comprising:

a member formed of a beta-titanium alloy composition and adapted to expand from an insertion dimension to a deployment dimension, said beta-titanium alloy composition having superelastic

characteristics for facilitating operation between the insertion dimension and the deployment dimension.

15. A medical device adapted for insertion into a cavity of a patient, comprising:

an elongated member formed of a beta-titanium alloy composition.

16. A method for deploying a stent for maintaining a dilated vessel in an opened non-occluded condition comprising:

providing a stent formed of beta-titanium alloy composition,

elastically deforming the stent to a low-profile diameter for insertion;

providing an elongated insertion device adapted to support the stent in an elastically-deformed low-profile diameter;

inserting the insertion device having the stent supported at a distal end thereof into a patient and locating the stent relative to a treatment site; and

deploying the stent in the body cavity.

17. The method of claim 16 wherein the insertion device restricts expansion of the elastically-deformed stent during insertion and allows expansion of the elastically-deformed stent for deployment.

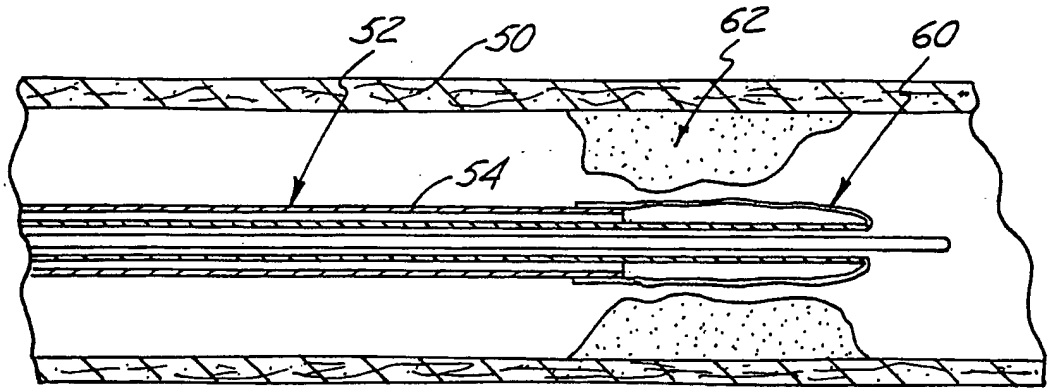

Fig. 1A

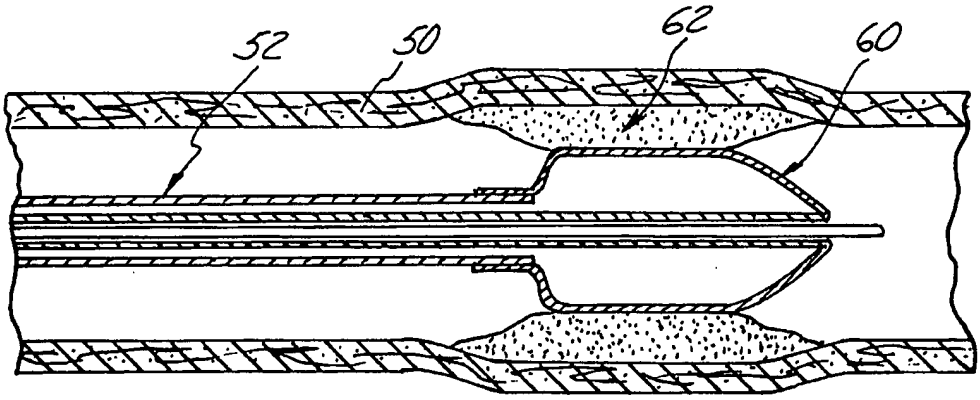

Fig. 1B

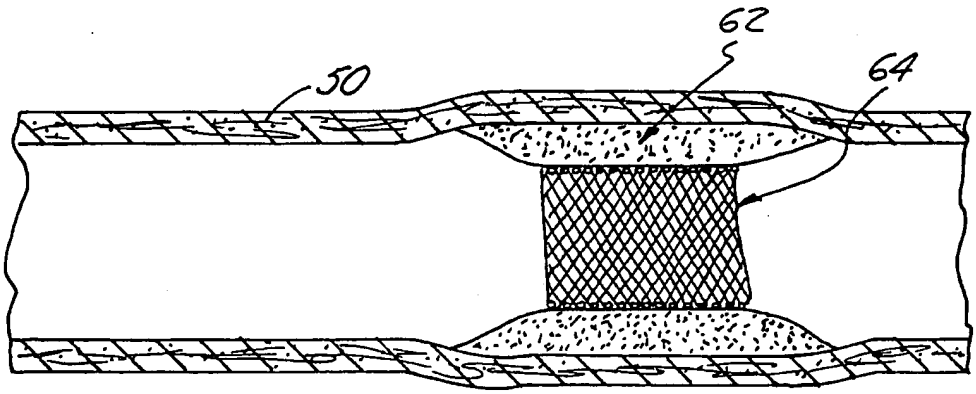

Fig. 1C

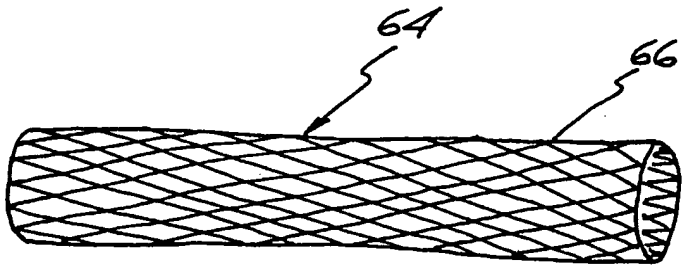

Fig. 2

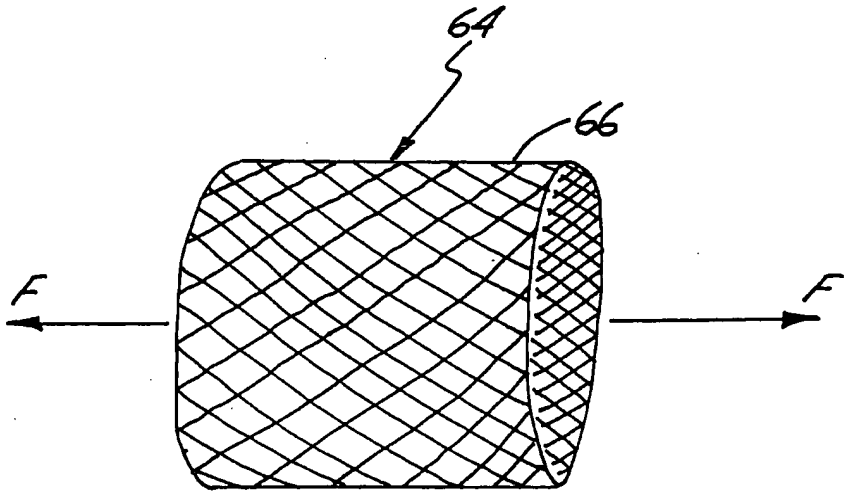

Fig. 3

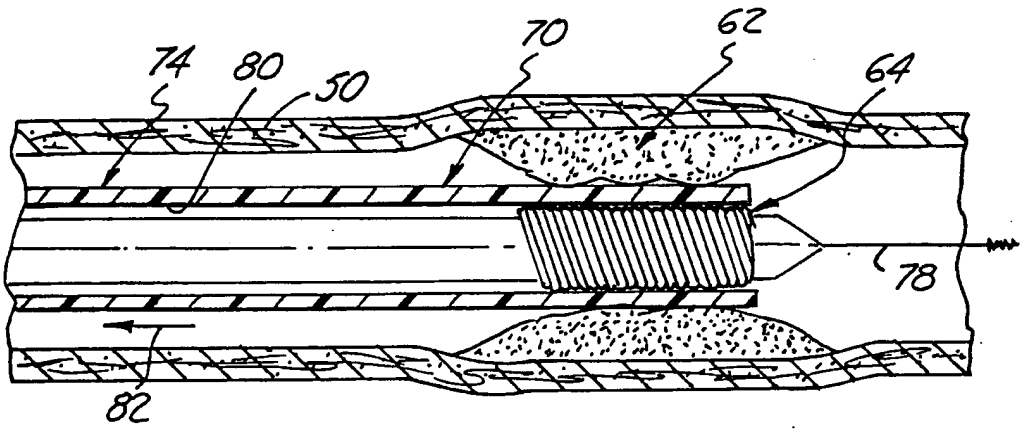

Fig. 4

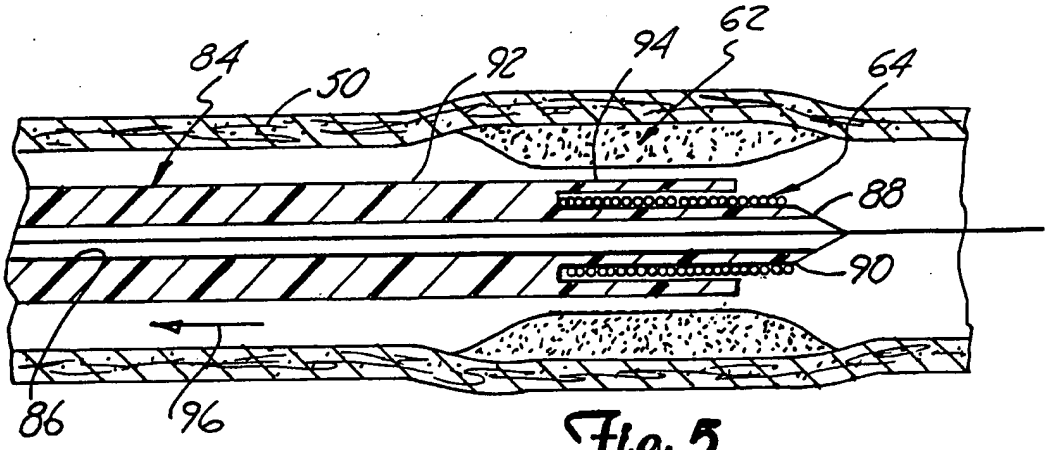

Fig. 5

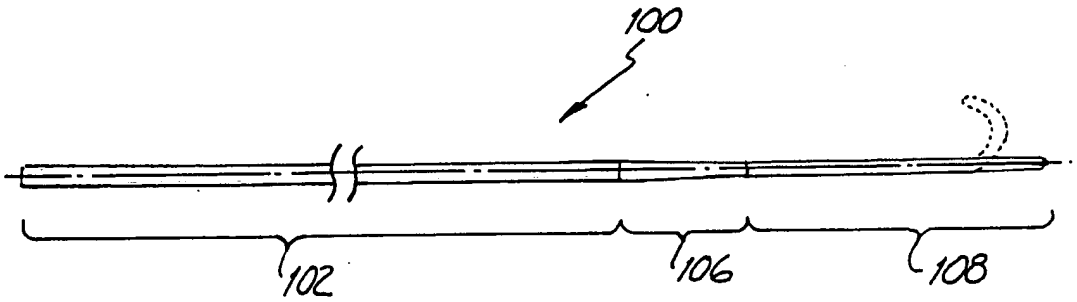

Fig. 6

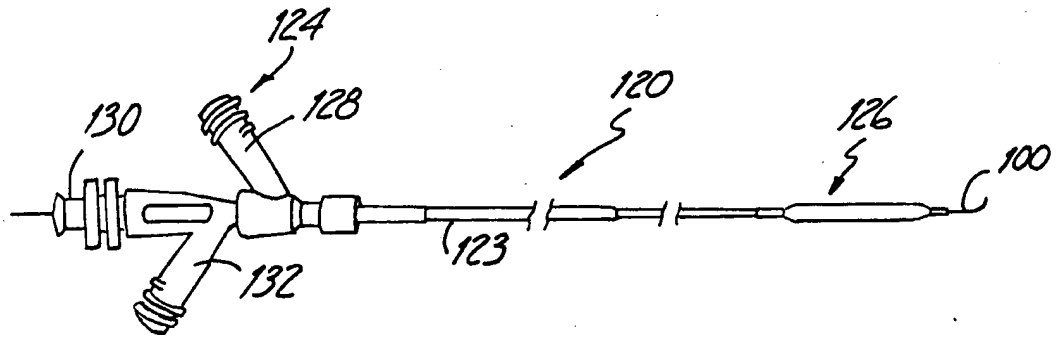

Fig. 7A

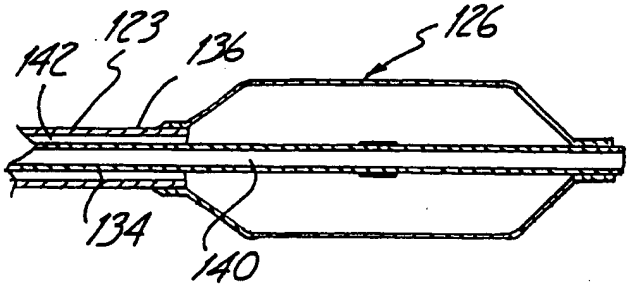

Fig. 7B

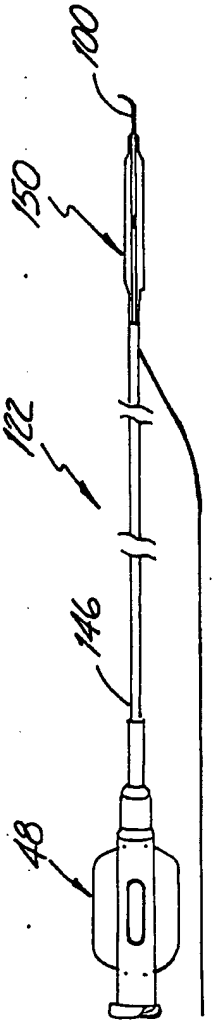

Fig. 8A

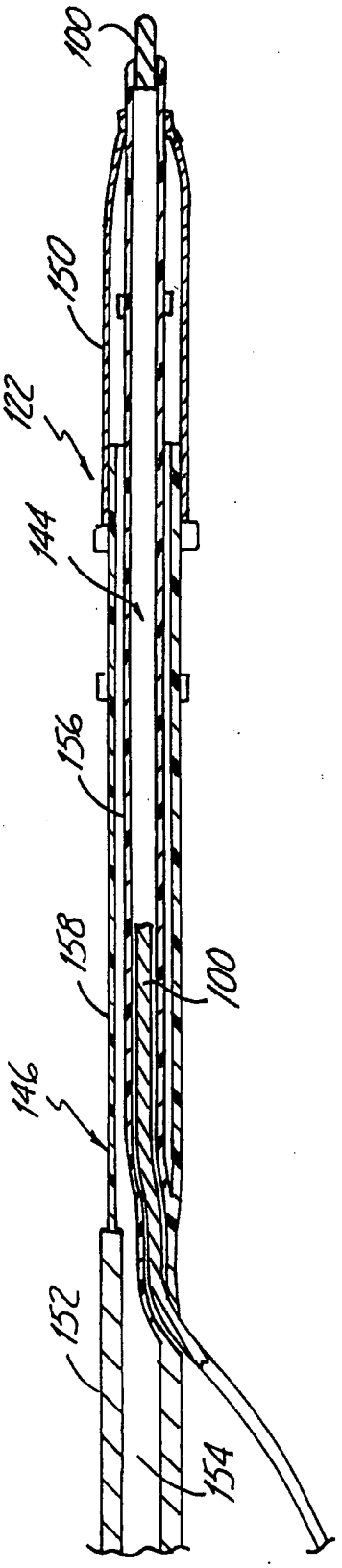

Fig. 8B

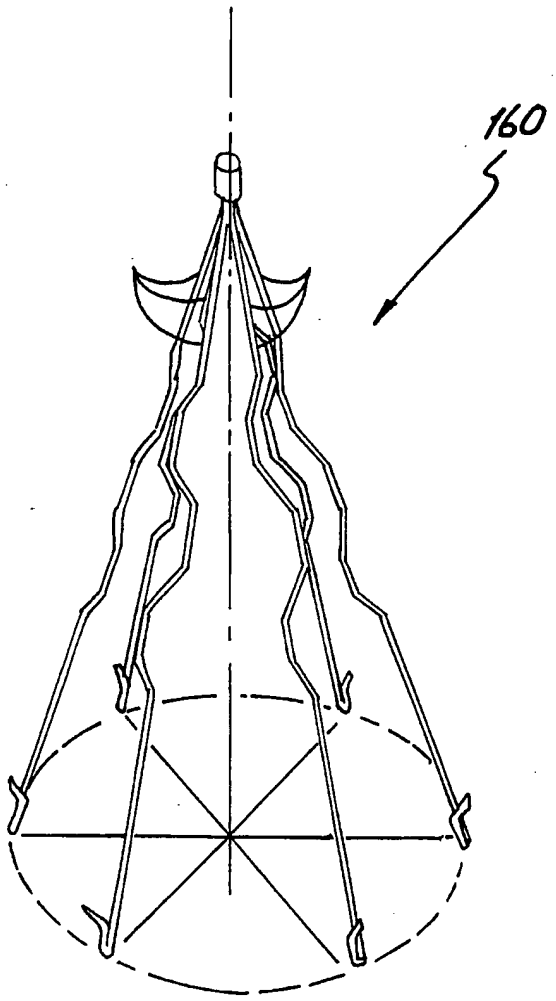

Fig. 9

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/09884

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61M 29/00
US CL :606/108, 198

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/108, 198.

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,545,210 A (HESS et al.) 13 August 1996, col. 4 lines 8-43.	1-17
Y, P	US 5,782,907 A (FRANTZEN et al.) 21 July 1998, col. 8 lines 9-38.	1-15
Y	US 5,238,004 A (SAHATJIAN et al.) 24 August 1993, col. 4 lines 5-36, and col. 5 lines 9-25.	1-15
Y	US 5,562,641 A (FLOMENBLIT et al.) 8 October 1996, col. 2 lines 61-68, and col. 4 lines 7-32.	1-15

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 30 JUNE 1999	Date of mailing of the international search report 16 JUL 1999
Name and mailing address of the ISA US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer (JACKIE) TAN-UYEN THI HO Telephone No. (703) 306-3421

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